K001139

MAY 1 0 2000

Appendix A: 510(k) Summary of Safety and Effectiveness

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device description

PREFACE™ Guiding Sheath
The guiding sheath has a large non-tapered lumen that allows for intravascular passage of catheters and infusion of heparinized normal saline. The sheath, with sideport tubing and valve, has a pre-shaped distal tip section with radiopaque brite tip. The guiding sheath is pre-shaped to facilitate catheter positioning.

Dilator
A dilator is provided to facilitate the percutaneous entry of the guiding sheath by forming an atraumatic transition from the skin through the subcutaneous tissue to the vessel.

Guidewire
A guidewire is provided for maintaining access to the puncture site upon removal of the sheath.

Appendix A: 510(k) Summary of Safety and Effectiveness, Continued

Intended use	The intended use of the PREFACE Guiding Sheath, non-braided and braided, is for the introduction of intravascular electrophysiology catheters into any cardiac chamber.
Indications statement	The PREFACE Guiding Sheath, non-braided and braided, is used for the introduction of intravascular electrophysiology catheters into any cardiac chamber.
Technological characteristics	The technological characteristics of the Modified device have not changed due to extended range of French sizes.
Performance data	The above verification testing included visual control, a bending test, and a tip/cannula pull test. All samples passed the acceptance criteria, unless otherwise specified in the reports.
Conclusion	Based on the 510(k) summaries and the 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the Modified device is substantially equivalent to the currently Marketed device under the Federal Food, Drug and Cosmetic Act.
Contact	Mary Adams Regulatory Affairs Manager Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765
Date	April 6, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2000

Ms. Mary Adams
Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K001139
Trade Name: PREFACE Guiding Sheath, Models 2-603M, 2-703M, 2-803M, 2-903M, 2-1003M, 2-1103M
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: April 7, 2000
Received: April 10, 2000

Dear Ms Adams:

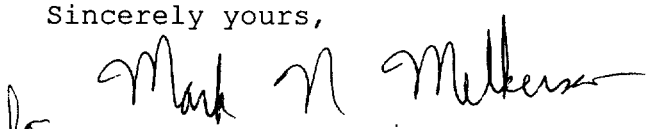
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix B: Indications for Use Statement

Statement

Indications for Use Statement:

510(k) Number: TBD

Device Name: PREFACE™ Guiding Sheath and PERRY Exchange Dilator

Indications for Use: The intended use of the PREFACE Guiding Sheath, non-braided and braided, is for the introduction of intravascular electrophysiology catheters into any cardiac chamber.

for (Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001139